STONY BROOK
STATE UNIVERSITY OF NEW YORK
UNIVERSITY HOSPITAL AND MEDICAL CENTER

Department of Medicine
Division of Endocrinology/Metabolism

October 3, 2000

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Docket No. 00D-1307

Dear Sir:

This letter is in reference to the draft report for Guidance of Industry in developing PTH for the prevention and treatment of osteoporosis. I have reviewed the document and believe that the cautionary measures are appropriate. I would think that a way of screening for this very rare tumor should be standarized. Given that this tumor is so rare, a rather large number of subjects will need to be studied over several years. This problem would not be manifest in short term clinical trials. I assume this is the case since I am not aware of any mention of this from some of the phase I clinical trials with PTH. An elevation in alkaline phosphatase can be seen with many conditions including osteoporosis. This is a very broad exclusion criteria. Will the FDA require the Companies to state specifically what will be done if a participant developes an elevated alkaline phosphatase after starting treatment?

These are some thoughts about the draft document. If the results are to be useful, I think uniformity will be necessary.

Thank you for your consideration.

Sincerely,

Marie Gelato

Marie C. Gelato, MD,PhD
Professor of Medicine
Member FDA Advisory Board for
Endocrine and Metabolic Drugs

00D-1307

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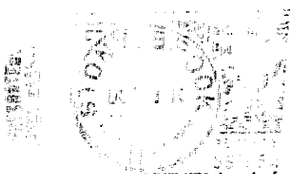

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